REMARKS

Claims 21-44 are pending in this application. Claims 21, 29 and 37 have been amended. The claim amendments are not narrowing, are supported by the application as filed, do not add new matter, and are otherwise proper. Applicants respectfully request entry of this amendment in its entirety.

In view of the amendment and following remarks, applicants respectfully request reconsideration of the application and claims and submit that the application is in condition for allowance.

DRAWINGS

The Office Action Summary sheet indicated that the proposed drawing correction filed on December 21, 2001, was disapproved by the Examiner. Applicants are unsure as to the basis for this disapproval because December 21, 2001, is the date this continuation application was filed, the Office Action provides no statements as to why the drawings were disapproved and no draftsperson's summary was provided with the Office Action. Accordingly, applicants respectfully request the Examiner indicate whether the drawings filed December 21, 2001, are acceptable, and, if not, provide the specific deficiencies in the filed drawings.

DOUBLE-PATENTING REJECTION

In the Office Action, claims 21-28 were rejected under 35 U.S.C. §101 as "claiming the same invention as that of claims 1-18 of prior U.S. Patent No. 6,358,939. This is a double-patenting rejection." The Office Action also stated that "the term 'same invention' in this context, means an invention drawn to the identical subject matter." Applicants respectfully disagree with this rejection, and note that claims 1-8 of U.S. Patent No. 6,358,939 are directed to "1,25-dihydroxyvitamin D_3." In contrast, claims 21-28 of the present application are directed to "1α-hydroxyvitamin D_3." 1,25-

dihydroxyvitamin D_3 and 1α-hydroxy Vitamin D_3 are not identical as they have different structures. Threfore, claims 21-28 of the present application are not drawn to the identical subject matter claimed in U.S. Patent No. 6,358,939 and are not the "same invention." Accordingly, applicants respectfully request the Examiner withdraw this rejection.

REJECTION UNDER 35 U.S.C. §103

In the Office Action, claims 21-44 were also "rejected under 35 U.S.C. 103(a) as being unpatentable over Snowden (U.S. Patent No. 6,214,373)." Applicants respectfully traverse this rejection. "When applying 35 U.S.C.103,the following tenets of patent law must be adhered to:

[(A)] The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; [and

(B)] Reasonable expectation of success is the standard with which obviousness is determined."

MPEP §2141.01

First, Snowden provides no suggestion or motivation to focus on vitamin D as the primary agent for treating inflammatory bowel disease as in the claimed invention. Snowden discloses "an oral multinutrient composition" that "combines in a mixture, selected vitamins, [and] also includes selected minerals[.]" Column 5, line 1 and column 4, lines 60-64. Snowden's "multinutrient composition" contains at a minimum vitamin A, vitamin E, vitamin K and several minerals in addition to vitamin D. One skilled in the art would recognize that these additional vitamins and minerals are required in Snowden's composition because that composition was "specially formulated to meet the special nutritional needs of individuals who do not obtain sufficient quantities of certain of the **essential vitamins and minerals** from their diet." Column 5, lines 1-4 (emphasis added). Exemplary compositions disclosed by Snowden also include a host of B vitamins, vitamin C, iron, calcium, zinc, selenium, copper, iodine and manganese. See, *e.g.*, Tables 1 and 2. Snowden does not direct the skilled artisan to focus specifically on vitamin D as a treatment for inflammatory bowel disease but instead teaches away from such a

treatment because Snowden requires a combination of vitamins and minerals. In contrast, the present invention claims treating inflammatory bowel disease with compositions that can contain only 1α-hydroxyvitamin D_3, 1α-hydroxyvitamin D_2, or 19-nor-1,25-dihydroxyvitamin D_2. The claimed invention does not require any other vitamins or minerals to be present for treating inflammatory bowel disease, although the claims do not exclude such components.

Additionally, the present inventors have discovered that the underlying symptoms of inflammatory bowel disease, for example inflammation, are capable of being effectively treated with active vitamin D compounds. Snowden on the other hand only discloses a composition that helps to treat nutritional deficiencies which result from inflammatory bowel disease that cause inefficient uptake of vitamins and minerals. Nowhere does Snowden even contemplate that the underlying symptoms of inflammatory bowel disease can be treated with vitamin D compounds as can occur with the claimed invention. Moreover, one skilled in the art would not believe that focusing only on vitamin D could be reasonably expected to provide success for treating inflammatory bowel disease because Snowden's entire focus is on a combination of vitamin and minerals. Therefore, the skilled artisan would not find the claimed invention that focuses specifically on treatment of inflammatory bowel disease using vitamin D compounds obvious in light of Snowden. Accordingly, applicants respectfully request the Examiner withdraw this rejection.

Applicants reserve the right to remove this reference as prior art by filing an appropriate declaration under 37 C.F.R. 1.131.

CONCLUSION

In view of the above remarks, it is respectfully submitted that this application is in condition for allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to telephone the undersigned at the number listed below if the Examiner believes such would be helpful in advancing the application to issue.

Respectfully submitted,

Date April 28, 2003

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

21. (Amended) A method of treat[ment]ing inflammatory bowel disease, comprising: [a) providing:

i) a subject with symptoms of inflammatory bowel disease, wherein said inflammatory bowel disease is selected from the group consisting of ulcerative colitis and Crohn's disease, and

ii) a therapeutic composition comprising a biologically active vitamin D compound, wherein said biologically active vitamin D compound is 1α-hydroxyvitamin D_3; and

b)] administering a therapeutically effective amount of [said] a therapeutic composition [to] comprising [said] 1α-hydroxyvitamin D_3 to a subject suffering from the symptoms of inflammatory bowel disease, wherein said inflammatory bowel disease is selected from the group consisting of ulcerative colitis and Crohn's disease [under conditions such that said symptoms are reduced].

29. (Amended) A method of treat[ment]ing inflammatory bowel disease, comprising: [a) providing:

i) a subject with symptoms of inflammatory bowel disease, wherein said inflammatory bowel disease is selected from the group consisting of ulcerative colitis and Crohn's disease, and

ii) a therapeutic composition comprising a biologically active vitamin D compound, wherein said biologically active vitamin D compound is 1α-hydroxyvitamin D_2; and

b)] administering a therapeutically effective amount of [said] a therapeutic composition [to] comprising [said] 1α-hydroxyvitamin D_2 to a subject suffering from the symptoms of inflammatory bowel disease, wherein said inflammatory bowel disease is selected from the gr up consisting of ulcerative colitis and Cr hn's diseas [under conditions such that said symptoms are reduced].

37. (Amended) A method of treat[ment]ing inflammat ry bowel disease, comprising: [a) providing:

i) a subject with symptoms of inflammatory bowel disease, wherein said inflammatory bowel disease is selected from the group consisting of ulcerative colitis and Crohn's disease, and

ii) a therapeutic composition comprising a biologically active vitamin D compound, wherein said biologically active vitamin D compound is 19-nor-1α,25-dihydroxyvitamin D_2; and

b)] administering a therapeutically effective amount of [said] a therapeutic composition [to] comprising [said] 19-nor-1,25-dihydroxyvitamin D_2 to a subject suffering from the symptoms of inflammatory bowel disease, wherein said inflammatory bowel disease is selected from the group consisting of ulcerative colitis and Crohn's disease [under conditions such that said symptoms are reduced].